Study Title: OPV Transmissibility in Communities After Cessation of Routine OPV Immunization

NCT Number: 02376374

Latest Continuing Review Approval by IRB Committee: 7/31/2018

Summary of Study Protocol

Stanford will not participate in the actual consent procedure. The Stanford study team will be involved in all aspects of the study preparation and design, and will perform the OPV detection assay on all stool specimens collected during the field study.

Although the Stanford study team will not be actually consenting subject, the procedures that will be followed by our Mexican collaborators are as follows.

During the study preparatory period prior to the February 2015 NIW, the Mexican field study team will conduct a census of Mariano Escobedo municipality in order to identify the geographic bounds of 3 clusters of 150 households that each have one OPV-eligible child. Then, the field study team will go door-to-door in the community to inform and recruit eligible households. After reviewing our inclusion and exclusion criteria, study staff will go over the informed consent form with the parents and legal guardians of eligible households. Any lingering questions will be answered, and the parent can choose to enroll their household or not. If they choose to enroll, the parent will be asked a series of questions to populate the fields for our enrollment questionnaire. This contains questions regarding breastfeeding and other feeding history, the OPV-eligible child's history of illness, immunization history, family and home information, and travel history. Basic measurements of the child including height, weight, and head circumference will also be taken. The parents will then provide a sample of the child's stool.

In addition to enrollment of the child, individuals who live in the same household as each enrolled child will be enrolled as household contacts. These people can be of any age or relation to the enrolled child. Consent forms for the household contacts will have been given to the parent of the eligible child to discuss with his/her family prior to choosing to enroll. When the child is enrolled, the household members who have read the consent form and agree to participate will undergo informed consent. Study staff will go over the informed consent form with the household contacts. Any lingering questions will be answered, and the household contacts can choose to enroll or not. If any of the household contacts are children, their parents or legal guardians will sign the consent form. If any of the household contacts are children between the ages of seven and eighteen, the study staff will go over an assent form with them to complete and sign. If they choose to enroll, the household contacts will be asked a series of questions to populate the fields for our enrollment questionnaire. This contains questions regarding their health history, immunization history, and travel history. The household contacts will also provide a stool sample at enrollment.

Each household cluster will have OPV-vaccinated and non-vaccinated houses. Upon enrollment, households will be randomized to one of these 2 arms to achieve the desired vaccination

coverage rates (10%, 30%, 70%.) Within each OPV-vaccinated household, one eligible child will receive OPV during the February 2015 NIW. Our study team will not be administering the OPV.

Stool samples will be collected upon enrollment, and at 9 scheduled home visits (1 day after OPV, every 3rd day after OPV x 4 then every week x 3 with a final sample collected at week 10.) A short follow-up questionnaire that includes data about changes in health, feeding habits, travel, or vaccinations since the last visit.

Both the questionnaires and stool samples will be coded with a unique alpha-numeric identifier in order to protect subject health information and privacy. The key linking patient identifying information to the unique alpha-numeric identifier will be kept in a secure, locked cabinet and will only be accessed by research staff.

Final results from this study were written up into seven manuscripts that were featured in a special issue of Clinical Infectious Diseases dedicated to the polio eradication endgame titled, "Polio Endgame and Beyond: Vaccination Choices, Transmission Dynamics, and Surveillance Implications". The special issue was published open access and can be found here: https://academic.oup.com/cid/issue/67/suppl_1

The manuscripts related to this manuscript can be found below:

1. Sarnquist C, Holubar M, García-García L, et al. Protocol Paper: Oral Poliovirus Vaccine Transmissibility in Communities After Cessation of Routine Oral Poliovirus Vaccine Immunization. *Clin Infect Dis*. 2018;67(suppl_1):S115-S120. doi:10.1093/cid/ciy606

2. van Hoorebeke C, Huang C, Leary S, et al. Lab Protocol Paper: Use of a High-throughput, Multiplex Reverse-transcription Quantitative Polymerase Chain Reaction Assay for Detection of Sabin Oral Polio Vaccine in Fecal Samples. *Clin Infect Dis*. 2018;67(suppl_1):S121-S126. doi:10.1093/cid/ciy648

3. Altamirano J, Purington N, Behl R, et al. Characterization of Household and Community Shedding and Transmission of Oral Polio Vaccine in Mexican Communities With Varying Vaccination Coverage. *Clin Infect Dis*. 2018;67(suppl_1):S4-S17. doi:10.1093/cid/ciy650

4. Jarvis CI, Altamirano J, Sarnquist C, Edmunds WJ, Maldonado Y. Spatial Analyses of Oral Polio Vaccine Transmission in an Community Vaccinated With Inactivated Polio Vaccine. *Clin Infect Dis*. 2018;67(suppl_1):S18-S25. doi:10.1093/cid/ciy622

5. Fu R, Altamirano J, Sarnquist CC, Maldonado YA, Andrews JR. Assessing the Risk of Vaccine-derived Outbreaks After Reintroduction of Oral Poliovirus Vaccine in Postcessation Settings. *Clin Infect Dis*. 2018;67(suppl_1):S26-S34. doi:10.1093/cid/ciy605

6. Altamirano J, Sarnquist C, Behl R, et al. OPV Vaccination and Shedding Patterns in Mexican and US Children. *Clin Infect Dis*. 2018;67(suppl_1):S85-S89. doi:10.1093/cid/ciy636

7. Altamirano J, Leary S, van Hoorebeke C, et al. Validation of a High-throughput, Multiplex, Real-time Qualitative Polymerase Chain Reaction Assay for the Detection of Sabin Oral Polio Vaccine in Environmental Samples. *Clin Infect Dis*. 2018;67(suppl_1):S98-S102. doi:10.1093/cid/ciy639